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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/777,211

02/13/2004

Markku Anttila

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

12/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/777,211	Applicant(s) ANTTILA, MARKKU	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments

1. The amendment filed on 9/2/08 has been entered.
2. The response filed on **9/2/08** has been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-5 and 7-13 are pending.
5. The rejection of claims 1-5 and 7-13 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn based on the remarks filed on 9/2/08.
6. The rejection of claims 1-5 and 7-9 under 35 U.S.C. 103(a) as being unpatentable over Biskobing with WO 97/32574 in view of Halonen et al. (US 6,245,819) further in view of Vasu, and Melander et al. is withdrawn due to Applicant's arguments.

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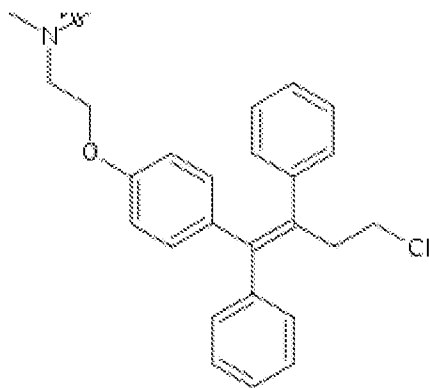
7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Antila Head & Neck Cancer, 1997 Abstract Number 1144 (Applicant's IDS Ref. # 2) as evidence by Kangas, Cancer Chemotherapy and Pharmacology, 27:8-12 (1990).

Antila discloses administering 60 mg/day of a metabolite toremifene to healthy



male volunteers Toremifene is taken orally with a meal (food) and

therefore reasonably meets the limitation of claims 1 because food would have

nutritional value and would reasonably inherently cause secretion of bile acids, and

inherently enhance bioavailability of toremifene. As stated in the MPEP

2112.01 "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable; therefore, the

bioavailability would be enhanced when taken orally with food. Antila teaches the food

is taken "with meal" and therefore anticipates the ranges recited in claims 3-5.

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Kangas is used to show that metabolites of toremifene result in ospemifene

TORÉ VI. See page 9, Fig. I.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 and 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Antila Head & Neck Cancer, 1997 Abstract Number 1144 in view of Blom et al. US 6984665 (priority 5/2/01) as evidence by Kangas, Cancer Chemotherapy and Pharmacology, 27:8-12 (1990), see page 9, Fig. I.

Antila is as described above. However, Antila does not teach treating osteoporosis or the compound ospemifene specifically as required by instant claims 2, 7 and 10-13.

For this reason Blom is introduced.

Blom teaches geometric isomer or a stereoisomer of instant compound (I) (as ospemifene) see abstract, as required by instant claims 1-2, 7, 10 and 12. Bloom further teaches administering 30-90 mg/day of ospemifene for the treatment of skin atrophy, vaginal symptoms and osteoporosis as (i.e., as it relates to claims 7-9 and 10-12 (see abstract, col. 4, line 40 and col. 7, line 15).

With regard to instant claims 10 and 12 Blom teaches ospemifene as the Z-isomer see col. 3, lines 40-43. However, Bloom does not teach the administration of the drug with a meal.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant application to expand the teachings of Antila by administering to patients suffering from osteoporosis as taught by Blom. One of ordinary skill in the art would have employed the teachings of Antila supra and expanded the administration of the drug to include metabolites, such as ospemifene as taught by Blom. In summary, one of ordinary skill in the art would have been motivated to combine the teachings of Antila with that of Bloom to include administration of toremifene and/or ospemifene for the treatment of osteoporosis and skin atrophy because Bloom teaches that ospemifene can be administered to treat the varying disorders discussed supra. Thus the combination would have resulted in the claimed invention.

9. Applicant argues that the effect of food intake on ospemifene absorption is 2-3 times higher than in fasted state. Applicant argues unexpected results to overcome the 103 rejection.

In Response: This is found not persuasive because the primary reference Antila specifically teaches administration with food. In order to overcome a 103 rejection based on an unexpected result, the result must be truly unexpected. Thus, consideration to the unexpected result is not persuasive for the reasons supra (as it relates to instant claim 8).

Maintained Double Patenting

10. The rejection of the above is maintained for the same reasons that the 103 rejection is maintained. In this instance Applicant alleging that the teaching of Antila is away from claimed invention is not persuasive. As evident by Melander et al, it would have been obvious to one of ordinary skill in the art to check the bioavailability of food effect on drugs before administration.

Claims 1 and 8-9 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent Application No. 11201098. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims require the compound-ospemifene is administered for the treatment of skin atrophy. As evident by Vasu, drugs are known in the art to be administered with food. With regard to Applicant's

arguing that the disclosure is to enhancing bioavailability will not change treating atrophy, because as soon as the drug is available treating will proceed.

11. Claims 1-9 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6984665. Although the conflicting claims are not identical, they are not patentably distinct from each other. As evident by Vasu, drugs are known in the art to be administered with food. With regard to Applicant's arguing that the disclosure is to enhancing bioavailability, as soon as the drug is bioavailable, treating skin atrophy will proceed.

Applicant argues that none of the applications or the patents applied in the rejections contains disclosure of enhancing bioavailability.

The scope as a whole is the same. Administering the drug with or without food is not going to change the mechanism of action of the drug in the system. Once the drug gets in the system it is available to proceed with said treatment. It would have been reasonable to expect an efficacious treatment modality would occur following "enhanced" bioavailability of the compound –ospemifene.

Careful thought have been given to the remarks, but are found unpersuasive and the rejection is maintained as in the office action on record.

12. No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. V. G./
Examiner, Art Unit 1618
11/13/08

/Robert C. Hayes/
Primary Examiner, Art Unit 1649